ATTACHMENT 1

K121549

510 (k) Summary

As Required by 21 section 807.92 (c)

DEC 27 2012

1. **Submitter Name:** Siam Sempermed Corp., Ltd
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   Songkhla. Thailand 90110
3. **Phone:** (+66) 74 344 663
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5. **Contract Person:** Mr. Anan Pruksanusak (Chief Operations Officer)
6. **Date summary prepared:** December 5, 2012
7. **Official Correspondent:** Sempermed USA Inc.
8. **Address:** 13900 49th Street North
   Clearwater, USA , FL 33762
9. **Phone:** 727-787-7250
10. **Fax:** 727-787-7558
11. **Contact person:** Mr. William E. Harris, III
12. **Device Trade or Proprietary Name:** Nitrile Examination Gloves with Aloe & Vitamin E, Powder-Free
13. **Device Common or usual name:** Examination glove
14. **Device Classification Name:** Polymer patient examination glove
15. **Device Class: Class 1**
16. **Product Code:** LZA
17. **Description of the Device:** Non-sterile, Powder-free Nitrile Examination Glove with Polymer coating, Aloe and Vitamin E, Blue.
18. **Intended use of the device:**
    This is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
19. **Predicate devices:**
    a. **K083755**: Non-Sterile, Powder-Free Nitrile Examination Glove with Polymer Coating. Tested for use with Chemotherapy Drugs [core glove].
    b. **K024121**: Non-Sterile, Powder-Free Latex Examination Gloves with Polymer Coating, Aloe, Vitamin E and Protein Claim (50 micrograms or Less) [Aloe & Vitamin E coating].
20. **Summary of the Technological Characteristics:**
    Non sterile, Powder free Nitrile Examination Glove with Polymer coating, Aloe, Vitamin E, Blue is substantially equivalent to the predicate devices. A side-by side comparison of the predicate devices with the subject device is presented in Table 1.

Table 1. Side-by-side Comparison of Predicate Devices with Subject Device

Device Description	**Predicate 1: K083755** Non-Sterile, Powder Free Nitrile Blue Examination Glove with Polymer Coating. Tested for use with Chemotherapy Drugs **[core glove]**	**Predicate 2: K024121** Non-Sterile, Powder-Free Latex Examination Gloves with Polymer Coating, Aloe, Vitamin E and Protein Claim (50 micrograms or Less **[aloe & vitamin E coating]**	**Subject device** Non-Sterile, Powder-Free Nitrile Examination Gloves with Polymer Coating, Aloe and Vitamin E, Blue	Substantial Equivalence
Intended Use	This is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	This is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	This is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	SE
Device Design	A protective garment that covers the hand and wrist with openings for fingers and thumb	A protective garment that covers the hand and wrist with openings for fingers and thumb	A protective garment that covers the hand and wrist with openings for fingers and thumb	SE
Primary Compound Used	Nitrile Synthetic latex	Natural Rubber Latex	Nitrile Synthetic Latex	SE
Single Use	Yes	Yes	Yes	SE
Ambidextrous	Yes	Yes	Yes	SE
Sterility	Not applicable	Not applicable	Not applicable	SE
Biocompatibility	Passes Primary Dermal Irritation in Rabbits and Guinea Pig Closed Patch Sensitization Test (ISO 10993-10)	Passes Primary Dermal Irritation in Rabbits and Guinea Pig Closed Patch Sensitization Test (ISO 10993-10)	Passes Primary Dermal Irritation in Rabbits and Guinea Pig Closed Patch Sensitization Test (ISO 10993-10)	SE
Dimensions	Meets ASTM D6319-10	Meets ASTM D3578-05	Meets ASTM D6319-10	SE
Tensile Strength	Meets ASTM D6319-10	Meets ASTM D3578-05	Meets ASTM D6319-10	SE
Ultimate Elongation	Meets ASTM D6319-10	Meets ASTM D3578-05	Meets ASTM D6319-10	SE
Freedom from Pinholes	Meets ASTM D5151-6	Meets ASTM D5151-6	Meets ASTM D5151-6	SE
Residual Powder	Meets ASTM D6124	Meets ASTM D6124	Meets ASTM D6124	SE
Polymer Coating	Yes	Yes	Yes	SE
Color	Lavender Blue	Natural	Blue	SE
Labeling	Includes chemotherapy claim	Includes Aloe and Vitamin E claim	Includes Aloe and Vitamin E claim	SE
Aloe & Vitamin E Coating	No	Yes	Yes. Same proprietary mixture as Predicate 2	SE

19. Conclusion:

The physical performance characteristics of the subject device (Non-Sterile, Powder free Nitrile Examination Glove with Polymer coating, Aloe, and Vitamin E, Blue) is substantially equivalent to predicate K083755 and will perform according to the glove performance standards referenced. Both are manufactured from the same nitrile synthetic latex material using the same production process. The subject device lacks the chemotherapy claim of predicate K083755. Although predicate K024121 is composed of natural rubber latex, it is treated with the same Aloe and Vitamin E coating mixture as the subject device. The subject device is therefore considered to be substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 27, 2012

Siam Sempermed Corporation, Limited
C/O Mr. William E. Harris
President and Chief Executive Officer
Sempermed USA, Incorporated
13900 49th Street North
CLEARWATER FL 33762

Re: K121549
Trade/Device Name: Nitrile Examination Gloves with Aloe & Vitamin E, Powder-Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: December 14, 2012
Received: December 20, 2012

Dear Mr. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 6

K121549

Indications for Use

510(k) Number (if known): K121549

Device Name: Nitrile Examination Gloves with Aloe & Vitamin E, Powder-Free

Device Description: Non-sterile, Powder-free Nitrile Examination Glove with Polymer Coating, Aloe, and Vitamin E, Blue

Indications For Use: This is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria Cruz-fisher

Digitally signed by Maria Cruz-fisher
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Maria Cruz-fisher, 0.9.2342.19200300.100.1.1=2000576169
Date: 2012.12.27 10:52:14 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number:_____